REMARKS

Status of the Claims

Claims 1, 2, 5-7, 9, 13-18, 21, 22, 24 and 26 are pending in the present application. Claims 1, 2 and 7 are amended. Claims 3, 4, 8, 10-12, 19, 20, 23, and 25 were previously canceled. Claim 15, 17, 22, and 24 are withdrawn as being directed to a non-elected invention. Claims 1, 2 and 7 are amended to recite "purifying IgG1, IgG2a, IgG2b, IgG3, and IgM antibodies". Support for these amendments may be found, for example on page 27, paragraph 2 of the originally filed Specification. Claims 1, 2 and 7 are also amended to recite "wherein the Fas function defects comprise a Fas ligand defect or a mutated Fas gene." Support for these amendments may be found, for example in the Specification as originally filed at page 6, beginning at line 11. New claims 27-32 are added. Support for new claims 27-32 may be found, for example, on page 28, lines 2-8, and original claim 5 of the instant application. No new matter is entered by way of this amendment. Reconsideration is respectfully requested.

Issues Under 35 U.S.C. § 112, first paragraph

New Matter

Claims 7, 9, 14, and 18 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly describing new matter. Specifically, the Examiner states that the term "native" is not a part of the originally filed application, *see* Office Action, page 2.

Applicants submit that the claims no longer recite the term "native", and thus the rejection is moot. Applicants respectfully request that the rejection be withdrawn.

Enablement and Written Description

Claims 1, 2, 5-7, 9, 13, 14, 16, 18, 21 and 26 are also rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement, or in the alternative, as allegedly failing to comply with the written description requirement, *see* Office Action, pages 3-5. Specifically, the Examiner alleges that the phrase "Fas function defects" is problematic. The Examiner asserts

that an ordinary artisan would not have known at the time of the invention what upstream or downstream genes could have led to Fas function defects. According to the Examiner, only two species of Fas function defects are supported by the present application, *i.e.*, Fas ligand defects and mutated Fas gene. In view of the foregoing, the Examiner does not believe that an ordinary artisan would have known how to make or envision mice comprising the allegedly broad genus of Fas function defects encompassed by the pending claims.

The claims recite that "wherein the Fas function defects comprise a Fas ligand defect or a mutated Fas gene". The Examiner acknowledges that the Specification teaches that both a Fas ligand defect and a mutated Fas gene, *see* Office Action, pages 3 and 4. Therefore, Applicants submit that the currently presented claims are amply supported by adequate written description and enablement. Applicants respectfully request that the rejections be withdrawn.

Issues Under 35 U.S.C. § 102(b)

Claims 7, 9, 14, 16 and 18 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 6,235,714 to Paul *et al.* ("'714"), *see* Office Action, pages 6-8.

Claim 7 recites that the claimed process further comprises "purifying IgG1, IgG2a, IgG2b, IgG3, and IgM antibodies". In contrast to claim 7, the '714 patent describes purifying IgG antibodies, *see*, *e.g.*, Example II. The '714 patent does not particularly describe purifying the specific IgG or IgM isotypes described in the current claims. Accordingly, the '714 patent does not anticipate the claims.

In view of the foregoing, independent claim 7 is not anticipated by '714. Further, dependent claims 9, 14, 16, and 18, which incorporate all of the elements of independent claim 7, are also not anticipated by '714. Accordingly, Applicants respectfully request that the rejection be withdrawn.

Issues Under 35 U.S.C. § 103(a)

Mashiko, Yamasaki, Makino, and Lage

Claims 1, 2, 5-7, 9, 13, 14, 16, 18, 21 and 26 are rejected under 35 U.S.C. § 103(a) as allegedly obvious over JP-01047390 to Mashiko *et al.*, ("Mashiko") or U.S. Patent No. 4,965,198 to Yamasaki *et al.*, ("Yamasaki"), each in view of Makino *et al.*, *J. Clin. Lab. Immunol*, 1988, 25:83-88, ("Makino"), and Lage *et al.*, *Virchows Arch*, 2001, 438:567-573, ("Lage."), *see* Office Action, pages 6-8. Applicants respectfully traverse.

Claims 1-2, 5-7, 9, 13-14, 16, 18, 21, and 26 are also rejected under 35 U.S.C. § 103(a) as allegedly being obvious over the '390 publication or the '198 patent, each in view of Lage and further in view of U.S. Patent No. 5,641,488 to Wysocki ("'488"), *see* Office Action, pages 10-12.

Specifically, the Examiner reiterates that the '390 publication and the '198 patent teach that it is preferable to immunize a mouse having an autoimmune disease, such as an NZB or MRL/I mouse, with an antigen having low immunogenicity, such as a glycolipid. The Examiner admits that the '390 publication and/or the '198 patent do not describe glypican. However, the Examiner states that Lage describes glypican-3 and further teaches that the immunogenicity of glypican-3 is low. According to the Examiner, it would have been obvious to one of ordinary skill in the art at the time of the filing to make monoclonal antibodies against glypican-3 using autoimmune mice. The Examiner asserts that an ordinary artisan would have been motivated to combine these references to solve a well known problem in the art, *i.e.*, the difficulty in producing mAb that specifically recognizes the weakly immunogenic or non-immunogenic GPC-3 in mice.

The Examiner cites Makino for teaching that MRL/lpr mice have a much higher level of serum IC than male BXSB mice at 13 weeks. The Examiner cites the '488 patent for teaching methods for producing an antibody that binds to a desired antigen using MRL/lpr/lpr animals.

Applicants note that claims 1, 2 and 7 recite that the claimed method further comprises "purifying IgG1, IgG2a, IgG2b, IgG3, and IgM antibodies".

Applicants submit that none of the cited references, either alone or in combination, teach or suggest a process for producing antibodies that includes purifying all of the antibody isotypes described in the proposed claims. The '198 patent only discloses purifying IgG2a, IgG3, and IgM antibodies from NZB mice, *see* column 12, line 68 in the '198 patent. Neither the '390 application, Makino, Lage, nor the '488 patent remedy this deficiency. Accordingly, the proposed claims are not rendered obvious by either of the described combinations of cited references.

In view of the foregoing, Applicants submit that the claims are not obvious in view of the combination of cited references. Withdrawal of the rejections is respectfully requested.

Based upon the foregoing, the claims are not obvious over the cited references. Accordingly, Applicants respectfully request withdrawal of the rejection.

CONCLUSION

In view of the above, Applicants believe that the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mary M. H. Eliason, Reg. No.58,303, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant(s) respectfully petition(s) for a three (3) month extension of time for filing a reply in connection with the present application, and the required fee of $1,110.00 is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

#47,604

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